January 20, 2014

Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

On January 8, 2014, FDA sent letters urging purchasers to only conduct business with compounding pharmacies that register as outsourcing facilities. FDA also sent a similar letter to State Governors, State Boards of Pharmacies, and State Boards of Health recommending that States encourage non-resident compounding pharmacies that ship compounded drugs into the State to register with FDA as outsourcing facilities.

As an association representing more than 3,600 pharmacists, technicians, students, and members of the compounding community who focus on the specialty practice of pharmacy compounding, the International Academy of Compounding Pharmacists (IACP) is very concerned with the premature nature of FDA’s most recent correspondence to stakeholders promoting conducting business with only 503B registered facilities. IACP has always supported and continues to support increased communications between the States and FDA. However, IACP has strong reservations with FDA sending a letter to State stakeholders encouraging conducting business with only facilities registered as outsourcing facilities when FDA has not yet finalized guidance, restrictions, and quality standards for these 503B outsourcing facilities.

Without such guidance, many questions are left unanswered resulting in confusion amongst compounding facilities and the public as to what 503B registered facilities can put into the marketplace, how they must conduct business when compounding sterile products, and who ultimately bears the duty of inspections particularly when a 503B registered facility is conducting both 503A and 503B compounding practices in one facility.

As such, IACP is very concerned that this state of confusion will result in a similar situation when FDA previously allowed facilities to register as a “FDA-registered” facility. As we heard during hearings following the NECC tragedy, the past registration caused wide-spread confusion amongst Boards of Pharmacy as to whether the registered facility fell under State Boards of Pharmacy purview or that of the FDA and whether all compounding practices within the registered facility fell under one governing body or whether split-jurisdiction was possible. We heard countless stories of State Boards of Pharmacy assuming that FDA possessed jurisdiction over the registered facility and the entirety of compounding practices that the facility conducted but where FDA pointed to the fact that State Boards of Pharmacy
bore responsibility for inspecting all compounding activities within these facilities. What we were left with was the possibility that facilities could skirt the inspection process.

IACP is very concerned that FDA appears to be going down a similar path by encouraging stakeholders to only do business with facilities registered as 503B facilities before FDA has finalized the restrictions and quality standards around these facilities. Registration, alone, does not mean that the facility has been inspected by the FDA, that the facility is in fact cGMP compliant, or that the facility is compounding safe medications. FDA recognized this very fact in its most recently released FAQ stating:

Registration means only that FDA has received the information required to register the facility. It does not mean that the facility is making FDA-approved drugs and it does not mean it is in compliance with current good manufacturing practice requirements, the other conditions of section 503B, or other requirements in the Act.1

Thus, even where FDA is acknowledging that registration alone does not guarantee safer compounded medications, that the facility has been inspected by FDA, or even that the facility is cGMP compliant, FDA nonetheless has sent out mass letters to all stakeholders encouraging conducting business with only 503B registered outsourcing facilities. Where FDA bears the duty of promoting public health, the most recent communications from FDA to stakeholders do not fulfill such duty. To the contrary, FDA is recommending that stakeholders conduct business with facilities that have fulfilled no other safety requirements except simply filling out paperwork to register with the FDA.

It is even more alarming that many of the recently registered facilities listed on FDA’s website have either not been inspected by the FDA at all or received disciplinary action after an inspection. The fact that FDA is recommending such entities before finalizing further guidance and quality standards for these facilities and, thus based solely upon the act of registration, promotes widespread public confusion all while doing nothing to promote the public’s health or prevent another NECC tragedy. As we have seen specifically with Ameridose during the NECC tragedy, registration with FDA alone does nothing to preserve the public’s health.

Therefore, IACP is very concerned that FDA’s most recent correspondence to stakeholders is premature and allows facilities to purport to the public to be FDA registered even while FDA has not finalized guidance or quality standards for these facilities. As such, IACP strongly encourages FDA to cease such correspondence and recommendations to stakeholders until FDA finalizes guidance and provides clear responses to the host of unanswered questions that currently exist regarding 503B outsourcing facilities.

Sincerely,

David G. Miller, R.Ph.
Executive Vice President & CEO

1 See http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm